REMARKS

Applicants appreciate Examiner Ramana's ongoing effort and consideration in what has turned out to be a prolonged prosecution. To this end, Applicants have made herein another bona fide attempt to advance prosecution of this application. Reconsideration of this application, as amended, is respectfully requested.

SECTION 112 REJECTIONS

The examiner has rejected the claims under Section 112 alleging written description support does not exist for the amendments made in Applicants's previous response. Applicants respectfully disagree and maintain that it is well known that subjecting a layer of UHMWPE to 10-150 KGy of gamma radiation results in uniform crosslinking throughout. The numerous references of record pointed out by Applicants in their previous response makes this clear. Notwithstanding, Applicants have removed the limitation from the claims. As such, the Section 112 rejections are now moot.

SECTION 103 REJECTIONS – DEVANATHAN/KREBS

Claims 49, 50, 52, 125-126, 128 and 129 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,645,594 to Devanathan et al. (hereinafter "Devanathan") in view of U.S. Patent No. 6,365,089 to Krebs et al (hereinafter "Krebs"). This rejection is a variation of numerous previous rejections in which the claims were rejected over a combination of Devanathan and U.S. Patent No. 6,165,220 to McKellop et al (hereinafter "McKellop"). However, Krebs and McKellop stand for the same general notion – using a shield to create surface gradient crosslinking with ebeam radiation.

I. Amendments to Claims 49 and 125 and Newly Added Claims 133 and 134

Applicants have herein amended the independent claims to recite that the crosslinked layers are free-radical quenched layers. Support for this limitation is found, amongst other locations of Applicants' specification, on page 12, lines 21 and 22 ("Such preforms may be quenched or non-quenched"); page 13, lines 6-8 ("It should be appreciated that the starting materials (e.g., the preforms, powders, or porous structures) may be "pre-irradiated", "pre-quenched", or otherwise preconditioned prior to use thereof"); and the Examples (where annealed UHMWPE is used).

Newly added claims recite that such free-radical quenched polyethylene comprises annealed polyethylene. Each of newly added claims 133 and 134 corresponds to the elected invention from the restriction requirements issued in this application. In addition, each of newly added claims 133 and 134 is readable on the elected species.

II. Applicants' Invention of Amended Claims 49 and 125

The composite prosthetic bearings of Applicants' independent claims 49 and 125 are not formed by surface-gradient crosslinking, but rather are fabricated by molding separate layers of polyethylene to one another. In the case of independent claim 49, a layer of crosslinked, free-radical quenched polyethylene is molded to a non-crosslinked layer of polyethylene, whereas in the case of independent claim 125, a first layer of polyethylene that is crosslinked to a first degree and free radical quenched is molded to a second layer of polyethylene that is crosslinked to a second, different degree and free radical quenched.

The idea of creating such a composite by molding two distinct layers to one another (i.e., one crosslinked the other non-crosslinked or lesser crosslinked) is in sharp contrast to the prior art. Indeed, it was Applicants who first realized that the tensile properties associated with the melt-fused interface between crosslinked and non-crosslinked polyethylene are as strong as at least the weaker of the individual layers (kindly see TABLE I and TABLE II, and the

associated discussion, from Applicants' specification for a better understanding of this notion). This is in contrast to earlier beliefs that the flowability limitations of crosslinked polyethylene rendered it unsuitable for molding to other materials. To wit, note the first four lines of column 5 of McKellop where it is noted that the gradual transition associated with gradient crosslinked polyethylene of McKellop's method is preferred "so that there is not a weak interface that could delaminate, i.e., due to a sudden change from crosslinked to non-crosslinked material." Applicants have overcome these existing misbeliefs.

The prolonged nature of this prosecution substantiates this unexpected result. Namely, despite repeated Office Actions and searching, the Office has not been able to locate a reference that teaches the formation of a laminar composite of the two distinct layers (i.e., one crosslinked, the other either non-crosslinked or lesser crosslinked). Instead, the Office relies on a reference that teaches composite molding of two similar layers (Devanathan – two or three non-crosslinked layers molded together) in combination with a reference teaching surface gradient crosslinking (currently Krebs, previously McKellop). As will be discussed in greater detail below, with all respect due the Office, this combination belies an understanding of the prior art as a whole and is fabricated from hindsight.

III. The Devanathan/Krebs Combination

Despite substituting the secondary reference (i.e., Krebs for McKellop), the current rejection is the same as numerous previous rejections. Namely, in the 3/5/09 Office Action, the Examiner indicated:

> "...it would have been obvious to one of ordinary skill in the art at the time the invention was made to have irradiated the articulating surface of the Devanathan et al. bearing with e-beam irradiation, as taught by Krebs et al., to produce cross-linking on its articulating surface for wear resistance."

In other words, the Examiner proposes to take Devanathan's molded, finished composite bearing and subject it to e-beam irradiation, as taught by Krebs. Apparently, the sole reasoning for doing this is "for wear resistance".

IV. The Combination Lacks a Legally-Sufficient Reasoning

As cited numerous times during this prosecution, the Supreme Court's KSR decision reiterated, amongst many other things, two fundamental tenets of patent law: (1) no proper analysis can support a finding of obviousness when the rejection fails to consider the prior art as a whole, and (2) no proper analysis can support a finding of obviousness when the prior art actually teaches away from the proposed combination. Respectfully, the current rejections, like the ones before them, are contrary to both of these notions.

As noted above, the sole reasoning provided throughout this prosecution for the application of surface gradient crosslinking to Devanathan's implant has been "for wear resistance". With all respect, such an analysis fails to consider the prior art as a whole, including its numerous teachings against such a combination. Applicants have on numerous occasions facilitated an understanding of the prior art as a whole throughout this long prosecution. Without rehashing the same in significant detail, Applicants respectfully remind the Examiner of the following key points:

> (1) Devanathan is directed to a method of fabricating orthopaedic bearings that leads to bearings that have "increased stiffness in the cup" and "reduced compression creep" relative to previous production techniques. See, e.g., column 2, lines 38-45. To do so, the inventive concept of Devanathan adds PMMA to the UHMWPE used to fabricate the bearing. In such a way, a bearing is produced that has increased stiffness and increased creep resistance.
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> (2) It is well known that while crosslinking leads to increased wear resistance, it can also lead to the reduction of stiffness and creep resistance. McKellop acknowledges that crosslinking can lead to reduced stiffness. See, e.g., column 4, lines 30-33 where McKellop describes that crosslinking can lead to

a reduction in the Young's modulus of polyethylene (Young's modulus is a measure of the stiffness of a given material). See also the Background of the present application where it is acknowledged that conventional (i.e., non-crosslinked) UHMWPE possess superior creep resistance relative to crosslinked UHMWPE.

(3) Similar to UHMWPE, the creep resistance of PMMA is likewise reduced when it is subjected to radiation. See, e.g., FIG. 4 of Peschanskaya and its associated discussion ("Deformation of Poly(methyl methacrylate) after Exposure to Radiation and Magnetic Fields by Peschanskaya et al. filed in an IDS dated May 28, 2008).

(4) The benefits of crosslinking UHMWPE have been known since the mid-70's, some twenty years before the filing of Devanathan. See, e.g., Li (U.S. Patent No. 6,794,423) column 2, lines 27-29. Yet, Devanathan is silent as to the use of irradiation to crosslink his acetabular cups.

(5) The art of record establishes the commonly known need to quench UHMWPE to remove free radicals therefrom subsequent to irradiation crosslinking, typically by annealing. See, e.g., Li at column 2, lines 57-65; Krebs column 2, lines 20-30; and Scott (U.S. Patent No. 6,547,828) column 4, line 66 through column 5, line 4.

(6) As described above, Devanathan's acetabular cup consists of significant amounts of PMMA. To radiation crosslink the finished acetabular cup of Devanathan would require post-irradiation annealing at a temperature which closely coincides with the melting temperature of PMMA. Unlike UHMWPE which remains workable above its melting temperature, PMMA turns to a liquid (with the approximate viscosity of honey) above its melting temperature. As such, post-irradiation quenching would completely distort, and effectively destroy, Devanathan's acetabular cup.

(7) The art of record establishes a prior misbelief that flowability limitations of crosslinked polyethylene rendered it unsuitable for molding to other materials. See, e.g., the first four lines of column 5 of McKellop where it is noted that the gradual transition associated with gradient crosslinked polyethylene of McKellop's method is preferred "so that there is not a weak interface that could delaminate, i.e., due to a sudden change from crosslinked to non-crosslinked material."

The above summary paints a picture of the prior art as a whole that is very different then the overly-simplistic analysis provided in the rejections of record. Indeed, while it would be easy to simply conclude that because one reference or another teaches the benefits of irradiating an orthopaedic bearing that it would therefore be obvious to irradiate all orthopaedic bearings, such a conclusion would belie an understanding of the prior art as a whole, and Devanathan in particular.

While it may be true that irradiating Devanathan's molded, finished composite bearing could result in increased wear resistance (as purported by the examiner), doing so is simply contrary to both common sense and the teachings of Devanathan. Indeed, as described above, Devanathan's acetabular cup consists of significant amounts of PMMA. No one skilled in the art would be motivated to radiation crosslink the finished acetabular cup of Devanathan, as proposed by the Examiner, ***since to do so would require post-irradiation annealing at a temperature which closely coincides with the melting temperature of PMMA. Unlike UHMWPE which remains workable above its melting temperature, PMMA turns to a liquid (with the approximate viscosity of honey) above its melting temperature.*** As such, post-irradiation quenching would completely distort, and effectively destroy, Devanathan's acetabular cup. Legally sufficient motivation cannot be found in such a circumstance.

Moreover, as pointed out above, the inventive concept of Devanathan is to add PMMA to a UHMWPE bearing to produce a bearing that has, amongst other things, increased creep resistance. ***With this in mind, no one skilled in the art would irradiate Devanathan's finished bearing, as proposed by the Examiner, since to do so would lead to a reduction in the creep resistance of both of the bearing's materials (i.e., UHMWPE and PMMA) and hence the overall bearing thereby destroying the very intent of Devanathan's invention of a bearing having increased creep resistance.*** Again, it is important to keep in mind that the benefits of crosslinking were well-known for over twenty years by the time of Devanathan's disclosure, yet

Devanathan chose not to incorporate crosslinking. ***To simply conclude that it would be obvious to radiation crosslink Devanathan's bearing without any further analysis as to why one should do so in light of the specific teachings against doing so cannot survive legal scrutiny.***

In previous Office Actions, the examiner responded with "[i]t is the Examiner's position that even if the crosslinking were to extend into layer 14, it would not destroy the bearing for its intended use since there is an additional layer 16 beyond 14." Respectfully, this is mere speculation that, again, fails to read the reference as a whole. There is nothing in Davanathan that concludes that the desired increases in creep resistance are only needed in layers 14 or 16 or that somehow not enjoying the benefits of increased creep resistance in layer 12 or 14 is somehow still within the inventive concept of Davanathan. There is simply no analysis on the record (or otherwise) to support the position that "kinda" destroying the intent of Devanathan in layer 14 is consistent with legal precedent since it "maybe" doesn't destroy the "entire" intent of Devanathan. Respectfully, the analysis is mere conjecture, with just as probable conjecture being that Devanathan chose not to incorporate the well-known technique of radiation crosslinking because he knew it was contrary to his goal of increased creep resistance.

V. The Proposed Combination Does Not Arrive at the Invention

As noted above, the independent claims have been amended to recite "crosslinked, free-radical quenched" layers of polyethylene. The proposed combination of a molded, finished composite bearing (as taught by Devanathan) that is subjected to e-beam irradiation (as taught by Krebs) does not teach such a limitation. Moreover, as pointed out above, nor would one skilled in the art do so since it would require post-irradiation annealing at a temperature which closely coincides with the melting temperature of PMMA. Unlike UHMWPE which remains workable above its melting temperature, PMMA turns to a liquid (with the approximate viscosity of honey) above its melting temperature.

Moreover, as previously established on the record, because the composite prosthetic bearings of Applicants' independent claims 49 and 125 are not formed by surface-gradient crosslinking, but rather are fabricated by molding separate layers of polyethylene to one another along a melt-fused interface (e.g., "wherein non-crosslinked polyethylene of the non-crosslinked layer of polyethylene is fused to crosslinked polyethylene of the crosslinked layer of polyethylene at the melt-fused interface"), an interface is formed by the entanglement of the molecules or molecular chains of one dissimilar polyethylene layer with the other. The proposed combination of a molded, finished composite bearing (as taught by Devanathan) that is subjected to e-beam irradiation (as taught by Krebs) does not teach such a limitation. In particular, although Krebs purports to allow some degree of control over the penetration depth via the use of shields (as did McKellop before it), there is no teaching in Krebs or Devanathan that teaches the concept of setting the ebeam penetration depth to coincide with any one of the mold interfaces of Devanathan. Moreover, the record is completely devoid of why one skilled in the art would even want to do so (without the benefit of hindsight, of course). This is especially true given the strong teaching of McKellop to the contrary. Namely, McKellop makes it clear that any "sudden change from crosslinked to non-crosslinked material" is to be avoided "so that there is not a weak interface that could delaminate". Even if it were possible (and the record does not make it clear that it is) to finely tune the teachings of Krebs to create the crosslinked/non-crosslinked transition at one of Devanathan's mold interfaces, such a teaching would hardly motivate one skilled in the art to do so since, according to McKellop's belief at the time, it would lead to delamination of the bearing. While it is true that the rejection is no longer based on McKellop (i.e., it is not being used by the examiner to reject the claims), the KSR court made it clear that a reference does not have to be part of the rejection to be relevant to the analysis of the prior art as a whole. In the case at hand, although the examiner has abandoned her previous rejections based on McKellop, the reference still remains instructive as to why one skilled in the art would not use

the teachings of Krebs to create the crosslinked/non-crosslinked transition at one of Devanathan's mold interfaces.

In short, neither Devanathan, Krebs, nor any combination thereof expressly or inherently teaches a melt-fused interface which defines the interface between the crosslinked polyethylene and the non-crosslinked polyethylene (or lesser crosslinked polyethylene). Nor would one skilled in the art believe it prudent to place such an interface in such a location since it was contrary to the teachings of the prior art.

VI. Conclusion Regarding the Section 103 Rejections

In short, the proposed combination of Devanathan and Krebs is flawed because it fails to consider the prior art as a whole, including aspects of the prior art that actually teach away from the proposed combination. Moreover, even if Devanathan and Krebs could be combined in the proposed manner, the resultant device would not arrive at the invention because it does not include crosslinked layers that are free-radical quenched, nor does it include a crosslinked layer and non-crosslinked layer (or lesser crosslinked layer) that are fused at a melt-fused interface.

REQUEST OF THE EXAMINER

As noted above, this paper reflects yet another bona fide attempt by Applicants to advance prosecution of this application. With this in mind, Applicants' undersigned counsel would very much appreciate the opportunity to discuss this case with the examiner should, after reading this paper, the examiner have thoughts as to what would put this application into a condition for allowance, or, in the alternative, a better condition for appeal.

REMINDER TO THE EXAMINER

In view of, and pursuant to, the holdings of the Federal Circuit Court of Appeals in the cases *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 66 U.S.P.Q.2d 1801 (Fed. Cir. 2003); *McKesson Info. Sol'ns v. Bridge Med.*, 487 F.3d 897, 927 (Fed. Cir. 2007); and related cases, Applicants hereby remind the Examiner of the existence of commonly-owned U.S. patent application serial nos.: 11/626,040 (pending) and 10/058,508 (now issued). Each of these applications has published (and in one case, issued) and is therefore publicly-available in PAIR. Moreover, the Patent Office has issued one or more Office Actions in each of these applications. The Examiner is invited to review the prosecution of these applications to determine its impact, if any, on the prosecution of the present application. In an effort not to overwhelm the Examiner with an overly large IDS, Applicants are not submitting copies of these publicly-available documents. Of course, Applicants would be happy to do so at the Examiner's request.

CONCLUSION

In view of the foregoing, it is submitted that this application is in a condition for allowance. Action to that end is hereby requested.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68002.

Respectfully submitted,
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